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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,313	01/25/2001	Chris W.M. Grant	P53-US2	4156

20988 7590 05/26/2004  
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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/768,313	<b>Applicant(s)</b> GRANT ET AL.	
	<b>Examiner</b> Chih-Min Kam	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/30/01</u> . | 6) <input type="checkbox"/> Other: ____.  |

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## **DETAILED ACTION**

### ***Oath/Declaration***

1. There is no oath or declaration in the file. An oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

### ***Claim Objections***

2. Claim 14 is objected to because of the use of the term “An acidic organic solvent as claimed in claim 13”. Since claim 14 is dependent from claim 13, the term “The acidic organic solvent as claimed in claim 13” should be used.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 15-18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 1-12 are indefinite because the claim lacks an essential step in the method of expression, purification and structural recovery of hydrophobic peptides. The omitted step is the step of transforming the host cell with a recombinant vector. Claims 2-10 and 12 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

6. Claims 1-12 are indefinite because of the use of the term “at least one of at least one stop codon contained within DNA sequence coding for the fusion protein” or “a fusion protein which contains.....peptide followed by either a stop codon contained within DNA sequence coding for the fusion protein...”. The term cited renders the claim indefinite, it is unclear what the term means as to “at least one of at least one stop codon”, and it is also not clear how a fusion protein, which contains a peptide that targets to bacterial inclusion bodies, a hexa-His tag and the desired hydrophobic protein, also have one stop codon contained within DNA sequence coding for the fusion protein. Claims 2-10 and 12 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

7. Claim 2 is indefinite because of the use of the term “TrpE”. The term “TrpE” renders the claim indefinite, it is unclear what the term represents. A fully spelled out word should be indicated.

8. Claims 4, 5, 7, 9 and 10 are indefinite because the claim is dependent from itself.

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9. Claims 15-18 provide for the use of an acidic organic solvent, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 1-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Jones *et al.* (Biochemistry 39, 1870-1878 (2000), published on Web 01/26/2000).

Jones *et al.* teach a pATH-New vector encoding a *TrpE*-Neu<sub>exp</sub> fusion protein was constructed by ligating a nucleotide fragment into a pATH11 expression vector, and the pATH-New vector was transformed into different strains of *E. coli* such as JM101, JM109, BL21 and DH5α for optimizing expression (claims 3-7 and 12), where Neu<sub>exp</sub> contains the transmembrane portion of the receptor tyrosine kinase, residues of Ala<sup>649</sup> to Met<sup>692</sup> of rat Neu and N-terminal hexa-His tag, and *TrpE* gene which encodes anthranilate synthase, and the fusion protein was expressed in a pATH vector to target expression product to inclusion bodies; the inclusion bodies was isolated and the fusion protein was cleaved by cyanogen bromide, if a methionine residue occurs within the desired peptide sequence, it would be necessary to replace this residue with other residues during PCR primer design if cyanogen bromide is to be used for fusion protein cleavage (page 1876, left column); the desired product, Neu<sub>exp</sub> was dissolved in 6 M guanidine

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hydrochloride, and purified on nickel chelate column; and the Neu<sub>exp</sub> product obtained after removal of guanidine hydrochloride was high oligomers, which was then dissolved in acidic organic solvent mixtures such as formic acid/glacial acetic acid/ chloroform/ethanol (FACE; ratio, 1:1:2:1) or formic acid/glacial acetic acid/ chloroform/trifluoroethanol (FACT; ratio, 1:1:2:1; claims 8-10, 13 and 14); and after removing the solvent and dissolving in SDS loading buffer, the gel band of the purified peptide produced by SDS-PAGE indicates the oligomeric complex has been dissociated into species with well-defined secondary structure, predominantly as monomers and dimers (pages 1871-1873; claims 1, 2, 11; 15-17). The reference also indicates acidic organic solvent mixtures, particularly FACT, were used to prepare solutions of lipid plus peptide for membrane assembly (page 1877, left column; claim 18).

### ***Conclusion***

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

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Chih-Min Kam, Ph. D.

*CMK*

Patent Examiner

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May 24, 2004